BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Customer:	Biogenique		
Product Name:	Biogenique Iron Bisglycinate		
Product Code:	N/A		
Product type:	Capsule		
Color/Size/Shape	Clear- Clear size "0" veggie Capsule filled with White powder with black particles powder.		
Product Packaging:	Bottles :200cc White HDPE 38/400, CAP: White 38/400 ribbed cap with HIS liner, Silica gel Pillow (0.5gram), Shrink Band 66X28mm,		
NPN	80142870		
Storage Conditions:	Store in cool, dry place.		
Allergen(s)	**Yes** □	**No** ■	**If yes, list:**
QA Approved By/Date:	 Jan.12,2026		

Ingredients		
List of Medicinal Ingredients	**Label Claim (mg)**	**Tolerance limits**
Iron (Iron (ii) bisglycinate)	25.00	Not Assayed. Product is manufactured quantification by input to contain 25.00 mg of Iron (Iron (ii) bisglycinate)
List of Non-Medicinal Ingredients		
Hypromellose, Microcrystalline cellulose		

Manufacturing Date	Jan.12,2026	**Biowell Lot #**	012617
Expiry Date	DE-2027		

BioWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Physical Tests- In-house			
Tests	**Method**	**Parameter**	**Results**
Appearance	**Visual**	**Clear- Clear size "0" veggie Capsule filled with White powder with black particles powder**	Clear- Clear size "0" veggie Capsule filled with White powder with black particles powder
Disintegration	**USP <2040>**	**NMT 45 min**	06 min
Target Net Content	**Scale**	**475.00 mg**	475.00 mg
Weight variation	**USP <2091>**	**580.0 mg (536.50-623.50) mg**	(536.50-623.50) mg
Locked Length	**Measurement**	**Size "0": 21.60 ± 0.3 mm**	(21.30 – 21.90) mm

Microbial-Tested on Finished Product			
Test	**Method**	**Parameter**	**Results**
Total Aerobic Microbial Count	**<USP 2021>**	**NMT 1000 CFU/g**	< 10 CFU/g
Total Yeast & Mold	**<USP 2021>**	**NMT 100 CFU/g**	<10 CFU/g
Salmonella spp.	**<USP 2022>**	**Absent in 10g**	Absent
E. Coli	**<USP 2022>**	**Absent in 10g**	Absent
Staphylococcus aureus	**<USP 2022>**	**Absent in 10g**	Absent
Microbial tolerance (limits) as per USP<2023> Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements, and USP<1111>Microbiological Examination of Nonsterile Products: Acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use			

Heavy Metal-Tested on Finished Product			
Arsenic	**USP<233>**	**<0.14 µg/kg b.w./day**	< 0.001 µg/kg b.w./day
Cadmium	**USP<233>**	**< 0.09 µg/ kg b.w./day**	< 0.001 µg/kg b.w./day
Lead	**USP<233>**	**< 0.14 µg/ kg b.w./day**	< 0.001 µg/kg b.w./day
Mercury	**USP<233>**	**< 0.29 µg/ kg b.w./day**	< 0.001 µg/kg b.w./day
Tolerance (limits) as per Appendix 3-General finished product specifications for NHP, Quality of NHP Guide			

Chemical- Tested on Finished Product			
Test	**Method**	**Parameter**	**Results**
Residual Solvents (Class III)	**USP <467>**	**Total: < 5000 ppm (<0.5% v/v)**	97 ppm (Refer to raw materials COAs)
Tolerance (limits) for Residual Solvents, Class III as per USP <467 and ICH Q3C >			

BIOWell Laboratories

FINISHED PRODUCT SPECIFICATION/ CERTIFICATE OF ANALYSIS

Product Disposition	Released ☑	Conditional Release ☐	Rejected ☐
QA Signature:		Date:	MAR. 23, 2026